IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PENNY BUSH,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

CIVIL ACTION

Case No._____

COMPLAINT AND JURY DEMAND

Plaintiff, Penny Bush, by and through her undersigned counsel, brings this action for damages against Defendant, Boston Scientific Corporation, and alleges as follows.

I. PARTIES

A. Plaintiff

1. Plaintiff, Penny Bush, is a citizen of Talking Rock, Pickens County, Georgia.

B. Defendant

2. Defendant, Boston Scientific Corporation ("Boston Scientific" or "Defendant"), is a corporation organized and existing under the laws of the State of Delaware. It maintains its corporate headquarters and its principal place of business at 300 Boston Scientific Way, Marlborough, MA 01752-1234.

3. All acts and omissions of Defendant as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

II. JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

5. Venue for this action lies in the United States District Court of Massachusetts, because the Defendant resides in this District and the wrongful acts upon which this lawsuit is based in part occurred in this District. Venue is also proper pursuant to 28 U.S.C. §1391(c) because Defendant has substantial, systematic, and continuous contacts in the District of Massachusetts, and it is subject to personal jurisdiction in this District.

III. DEFENDANT'S PELVIC MESH PRODUCTS

6. At all times material to this action, Defendant has designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. Each of these products was cleared for sale in the United States after the Defendant made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy. The Boston Scientific Obtryx Transobturator Mid-Urethral Sling System (Lot Number: 22517186) was implanted in Plaintiff.

6. The products include those known as Uphold Vaginal Support System, Pinnacle Pelvic Floor Repair Kit, Advantage Transvaginal Mid-Urethral Sling System, Advantage Fit System, Lynx Suprapubic Mid-Urethral Sling System, Obtryx Transobturator Mid-Urethral Sling Systems (I and II), Prefyx PPS System, Solyx SIS System, as well as any variations of these products and any unnamed Boston Scientific pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation.

7. The products also include Y-shaped mesh, which are vaginal mesh products that were more recently designed and marketed by Defendant. One such product is the Boston Scientific Upsylon Y Mesh product. Y-shaped mesh is inserted abdominally to support the pelvic organs.

8. All of these products are collectively referenced as Defendant's "Pelvic Mesh Products" or "Products." Any reference to "Pelvic Mesh Products" or "Products" should also be interpreted as a reference specifically to the Boston Scientific Obtryx Transobturator Mid-Urethral Sling System (Lot Number: 22517186).

IV. RISKS AND DANGERS OF THE PRODUCTS

7. At all relevant times, Defendant was in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, delivering, and introducing into interstate commerce—including, *inter alia*, within the United States, either directly or indirectly through third parties, subsidiaries, or related entities—Pelvic Mesh Products.

9. At all relevant times, Pelvic Mesh Products were used to treat pelvic organ prolapse and stress urinary incontinence.

10. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can

happen if the muscles that hold the pelvic organs in place become weak or stretched from aging, weight gain, childbirth, or any surgery, among other things. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel, and the rectum.

11. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress, like coughing, sneezing, or exercise.

12. Surgical mesh, including mesh used in Pelvic Mesh Products, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most Pelvic Mesh Products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh and/or collagen.

13. Despite claims that polypropylene mesh is inert, scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and, when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening, and anatomic deformation, and it can contribute to the formation of severe adverse reactions to the mesh.

14. Furthermore, Defendant's Pelvic Mesh Products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. The Pelvic Mesh Products cause adverse tissue reactions and are causally related to infection, as collagen is a foreign organic material. Mesh is harsh upon the female pelvic tissues. It hardens in the body and becomes inflexible, as does the scar tissue surrounding it.

15. When these Pelvic Mesh Products are inserted in the female body in accordance with the manufacturers' instructions, they create a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

16. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of stress urinary incontinence (SUI). These products include the Products manufactured, marketed, and distributed by Defendant. These Products are approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Pelvic Mesh Products.

17. On July 13, 2011, the FDA issued a warning regarding serious complications associated with pelvic mesh products, such as the Products manufactured, marketed, and distributed by Defendant. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." (emphasis original). The FDA had also received increased reports of complications associated with the Pelvic Mesh Products used in both pelvic organ prolapse and stress urinary incontinence cases.

18. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the

published scientific literature and in adverse event reports to the FDA. . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis original).

19. The FDA Safety Communication further indicated that the benefits of using Pelvic Mesh Products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

20. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

21. The FDA summarized its findings from its review of the adverse event reports and applicable literature by stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks" (emphasis original).

22. The White Paper further stated that "these products are associated with serious adverse events . . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper

concluded by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

23. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its petition, Public Citizen warned that pelvic mesh products should be recalled because they offer no significant benefits but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

24. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh. . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

8. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

25. As is known to the Defendant, the risks associated with POP repair are the same as risks associated with SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as

demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

26. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicate[] that serious complications can occur ... [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

27. Defendant did not, and has not, adequately studied the extent of the risks associated with the SUI repair Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks associated with the products used to repair SUIs.

28. Defendant knew or should have known that its Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing its Pelvic Mesh Products, Defendant was aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, Safety Communication. Despite claims that polypropylene mesh is inert, scientific evidence shows that this material as implanted in Plaintiff set forth below is biologically incompatible with human tissue. When used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues causes chronic inflammation

of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening, anatomic deformation, and scarring, and it can contribute to the formation of severe adverse reactions to the polypropylene mesh.

29. Complications from mesh placement for pelvic organ prolapse include, among other adverse events, acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. 15 Cosson, M., et al., *Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?* Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. **20**(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.* Am J Obstet Gynecol, 2008. **199**(6): p. 678 e1-4.

30. The Products were unreasonably susceptible to shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic wound healing, chronic infections in and around the mesh fibers, and nerve entrapment and scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

31. To this day, the Products continue to be marketed to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence and other competing products.

32. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Products and advertised, promoted, marketed, sold, and distributed the Products as safe medical devices. Defendant knew or should have known that the Products were not safe for their intended purposes and that the Products would cause, and did cause, serious medical problems—and in some patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

33. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications. They fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

9. All of this is true specifically with respect to the Product (i.e., the Boston Scientific Obtryx Transobturator Mid-Urethral Sling System (Lot Number: 22517186)) implanted into Plaintiff. The Products were brought to market by way of the FDA's 510(k) process in 2008.

34. The specific nature of the Products' defects includes, but is not limited to, the following:

a. The use of polypropylene in the Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

b. The design of the Products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden, leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-

implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, and chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. Biomechanical issues with the design of the Products which result in a nonanatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become scarred, eroded, inflamed, fibrotic, and infected, resulting in serious and permanent injury;

d. The propensity of the mesh design characteristics of the Products for plastic deformation when subjected to tension, both during implantation and once implanted inside the body, which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate, which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response, and chronic pain;

e. The propensity of the Products to become rigid and inflexible, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. The propensity of the Products for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a “barbed wire” or “saw blade” effect by the fragmented surface “sawing” through the tissue, leads to bacteria harboring in the fragmented, peeled, and split fiber surface, which in turn leads to chronic infections at the mesh surface and results in continuing injury over time;

g. The hyper-inflammatory responses leading to problems including chronic inflammatory response, chronic pain, and fibrotic reaction, as well as infections and other serious adverse events;

h. The harshness of mesh upon the female pelvic tissue and the hardening of the Products in the body; and

i. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

35. The Products are also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensity to contract, retract, and/or shrink inside the body;

b. The Products' inelasticity, preventing proper mating with the pelvic floor and vaginal region;

c. The frequency and manner of transvaginal mesh erosion or extrusion;

d. The risk of chronic inflammation resulting from the Products;

e. The risk of chronic infections resulting from the Products;

f. The risk of permanent vaginal or pelvic scarring as a result of the Products;

g. The risk of de novo urinary dysfunction;

h. The risk of de novo dyspareunia or painful sexual relations;

i. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

j. The need for corrective or revision surgery, or surgeries, to adjust or remove the Products, which in some cases is not feasible nor possible;

k. The severity of complications that could arise as a result of implantation of the Products;

l. The hazards associated with the Products;

m. The Products' defects described herein;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible, available and safer alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available, and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible, available and safer alternatives;

q. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible, available, and safer alternatives;

r. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

36. Defendant underreported and continues to underreport information about the propensity of the Products to fail and cause injury and complications and has made unfounded representations regarding the efficacy and safety of the Products through various means and media.

37. Defendant failed to perform proper and adequate testing and research prior to marketing and after introduction to the market in order to determine and evaluate the nature, magnitude, and frequency of the risks attendant to the Products.

38. Defendant failed to design and establish a safe, effective procedure for removal of the Products or to determine if a safe, effective procedure for removal of the Products exists.

39. Feasible, suitable, and safer alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

40. The Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

41. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

42. The Product implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession and in the condition directed by and expected by the Defendant.

43. At all relevant times herein, Defendant continued to promote the Products as safe and effective, even when no clinical trials had been conducted supporting long- or short-term efficacy or safety.

44. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks.

45. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by the implantation of the Products.

46. The Products as designed, manufactured, distributed, sold, and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

47. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh

contraction, infection, fistula, inflammation, scar tissue development, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, women who have suffered injuries like these, including Plaintiff, will need to be continuously monitored as a result of being implanted with Defendant's Products. A monitoring procedure exists for individuals experiencing physical and mental injuries from mesh implanted in patients with pelvic organ prolapse and/or stress urinary incontinence. The monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles. As such, Plaintiff is entitled to future medical monitoring and treatment directly related to the existing injuries caused by the defective products.

48. In many cases, including Plaintiff's, women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

49. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will continue to suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries because of implantation of Pelvic Mesh Products.

50. The medical and scientific literature studying the effects of Defendant's Pelvic Mesh Products—such as the effects of the Products implanted in Plaintiff—has examined each of

these injuries, conditions, and complications, and has reported that they are causally related to the Products.

51. Removal of contracted, eroded, and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

V. THE DISCOVERY RULE AND TOLLING OF LIMITATIONS PERIODS APPLY

52. Prescribing physicians, healthcare providers, and Plaintiff neither knew, nor had reason to know at the time the Products were implanted in her body, that they had the aforementioned defects. Ordinary consumers such as Plaintiff would not have recognized the potential risks or side effects which Defendants concealed through promotion of its Products as safe and effective for treating stress urinary incontinence and pelvic organ prolapse. Prescribing and implanting physicians likewise would not and could not recognize these risks because of Defendant's concealment of them through their marketing of the Products.

53. At all times described herein due to Defendant's marketing of the Products and Defendant's failures to correct the same, the Products were prescribed and implanted as intended by Defendant and in a manner reasonably foreseeable to Defendant. Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendant's failures to exercise reasonable care.

54. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Defendant's wrongful conduct caused her to suffer appreciable harm. Plaintiff could not, through the exercise of reasonable diligence, have discovered the wrongful conduct that caused her injuries at an earlier time. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the tortious nature of the conduct causing her injuries until a short time before filing of this action.

Additionally, Plaintiff was prevented from discovering this information sooner because: (1) Defendant has misrepresented to the public and to the medical community that its Products are safe for the treatment of stress urinary incontinence and pelvic organ prolapse; and (2) Defendant fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

55. The discovery rule tolls the running of the statute of limitations until Plaintiff knew, or in the exercise of reasonable care and due diligence should have known, of the cause of the injury, facts indicating that Plaintiff had been injured, and the tortious nature of the wrongdoing that caused the injury.

VI. ALLEGATIONS SPECIFIC TO PLAINTIFF

56. Plaintiff underwent surgery on or about August 16, 2019, at which time the Boston Scientific Obtryx Transobturator Mid-Urethral Sling System (Lot Number: 22517186) was implanted by Dr. Otto Umana, M.D., at Piedmont Mountainside Hospital Women's Center in Jasper, Georgia.

57. As a result of the mesh that was inserted, Plaintiff has suffered numerous injuries, including, but not limited to, mesh erosion and exposure, vaginal bleeding and discomfort, difficulty urinating, and dyspareunia.

58. Plaintiff underwent a mesh revision surgery on or about May 20, 2024. This surgery was performed by Dr. James Haley, M.D., at Cherokee Women's Health Specialists in Canton, Georgia.

59. Plaintiff has suffered significant pain, unnecessary expense, lost wages, embarrassment, disfigurement, and harm as a result of the implantation of Defendant's defective Product.

60. Plaintiff may have to undergo additional surgery in the future and may continue to suffer significant pain and unnecessary medical expense for medical care, treatment, and therapies long into the future.

61. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, and mental and physical pain and suffering, and she has incurred economic losses, which may continue far into the future.

VII. CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY
(GA. CODE ANN. § 51-1-11)

62. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

63. At all relevant and material times, Boston Scientific was the manufacturer of its Pelvic Mesh Products, including the Product that was implanted in Plaintiff. Boston Scientific designs, assembles, fabricates, produces, constructs, or otherwise prepares its Pelvic Mesh Products prior to selling the Products to health care professionals and other consumers.

64. The Product sold by Boston Scientific to Plaintiff and/or her physicians was new property.

65. Plaintiff was an intended consumer of the Product.

66. Plaintiff and her physicians' use of the Product was foreseeable. Indeed, the Product was implanted in Plaintiff in accordance with its intended and reasonably anticipated use.

67. The product that was implanted in Plaintiff was defective, both because of its design and because of its marketing and packaging. For this reason, the Product was not merchantable or

reasonably suited for its intended use (i.e., implantation within the body). The defective condition existed at the time the Product left Defendant's posession.

68. Boston Scientific owed Plaintiff a duty to ensure that there were no design defects in the Product that was implanted in Plaintiff.

69. The reasons that the Products were defective due to their design include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh, causing immune reactions and subsequent tissue breakdown, adverse reactions, and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for migration, erosion, and/or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation, walking);

g. the propensity of the Products to cause a chronic inflammatory and fibrotic reaction and result in continuing injury over time;

h. the propensity of the Products to cause longstanding inflammatory response altering the effective porosity of the mesh, resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage, and neuromas; and

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

70. Boston Scientific likewise owed Plaintiff a duty to select among reasonable and safer alternative designs for the Products. Safer alternative designs that would have prevented Plaintiff's injuries existed at the time when the Product left Boston Scientific's control. Specifically, the Products could have been designed to have a lighter weight, larger pore mesh, absorbable mesh, or to have biologic mesh inserts, among other safer alternatives. Such alternatives were technologically and economically feasible, and they would not have substantially affected the utility of the Products.

71. Boston Scientific should have adopted a safer alternative design in light of the likelihood of materialization and gravity of the risks associated with the Products and the minimal burden of an alternative design on the utility of the Products.

72. Boston Scientific likewise had a duty to warn Plaintiff and her physicians about the Products' dangers that they knew about, or should have known about, at the time the Products left Boston Scientific's control.

73. The Products were defective due to their marketing and packaging because Boston Scientific failed to provide adequate warnings about their dangerous characteristics, including, but are not limited to:

a. The Products' unacceptably high failure rate;

b. The Products' propensity to contract, retract, and/or shrink inside the body;

c. The Products' inelasticity, preventing proper mating with the pelvic floor and vaginal region;

d. The unacceptably high rate of infection and abscesses caused by the Products;

e. The unacceptably high rate of vaginal erosions and extrusions caused by the Products;

f. The unacceptably high rate of chronic pain caused by the Products;

g. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

h. The risk of chronic inflammation resulting from the Products;

i. The risk of permanent vaginal and/or pelvic scarring resulting from the Products;

j. The risk of de novo dyspareunia or painful sexual relations resulting from the Products;

k. Severe infections and urinary dysfunction caused by the Products;

l. The Products' propensity for migration;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available, and safer alternatives;

n. The necessity to remove the Products from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion, or other complications;

o. The difficulty in removing the Products from the patient's body, including the complete lack of a safe, effective procedure for full removal of the Pelvic Mesh Products;

p. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

q. Complete removal of the Products may not be possible and may not result in complete resolution of the complications.

74. After receiving notices of numerous bodily injuries caused by the Pelvic Mesh Products, Boston Scientific failed to provide the post-marketing or post-sale warnings or instructions regarding the substantial risk of harm associated with the Products to the physicians who implanted the Products or to the women who had been implanted with the Products. Such warnings should have conveyed that the Products were causing an unreasonably high rate of complications, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue formation, organ perforation, dyspareunia, bleeding, neuropathic and other acute and chronic nerve damage and pain, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapsed organs. Furthermore, Boston Scientific failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Products from the body in the event of product failure or other complications.

75. Boston Scientific knew or had reason to know of the foregoing conditions rendering the Products defective, both for reason of defective design and defective marketing and packaging. Therefore, the harm that Plaintiff sustained due to the Product's defective condition was foreseeable.

76. At no time did Plaintiff or her physicians have reason to believe that the Product was in a condition that was not suitable for its intended use among patients like Plaintiff. Plaintiff did not discover, nor could she have discovered through the exercise of reasonable care, that the Product was in a defective condition. Plaintiff could not have known that Defendant manufactured the Product in such a way as to increase the risk of harm to her.

77. As a direct and proximate result of Boston Scientific's wrongful conduct, including Boston Scientific's design, manufacture, labeling, marketing, sale, and distribution of its Pelvic

Mesh Products, both at the time of marketing and after the sale of the Product, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, and mental and physical pain and suffering. She has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses and lost income, and she has suffered other damages.

78. Boston Scientific has intentionally and/or recklessly designed, manufactured, marketed, labeled, sold, and distributed the Products with wanton and willful disregard for the health of Plaintiff and others. With malice, Boston Scientific placed their economic interests above the health and safety of Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory and punitive damages together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: NEGLIGENCE
(GA. CODE ANN. § 51-1-11)

79. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

80. Boston Scientific marketed its Products to and for the benefit of women, including Plaintiff, and also to her physicians.

81. Boston Scientific knew or should have known that the Products would be implanted inside women like Plaintiff. In fact, this was the intended purpose of the Products.

82. Boston Scientific owed Plaintiff a duty of reasonable care—in light of the generally recognized and prevailing best scientific knowledge—in designing, researching, labeling,

packaging, supplying, distributing, and selling its Pelvic Mesh Products, including the Product implanted in Plaintiff.

83. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Boston Scientific breached their duty to Plaintiff.

84. Boston Scientific breached its duty in negligently designing, labeling, packaging, and selling the Products, including the Product implanted in Plaintiff, by:

a. Failing to design the Products so as to avoid unreasonable risks of harm to the women in whom the Products were implanted, including Plaintiff;

b. Failing to use reasonable care in testing the Products, both before and after they were placed on the market, so as to avoid unreasonable risks of harm to the women in whom the Products were implanted, including Plaintiff; and

c. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging, and/or selling the Products.

85. The reasons that Defendant's negligence caused the Products to be unreasonably dangerous, defective, and unsuitable to be placed on the market include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh, causing immune reactions and subsequent tissue breakdown, adverse reactions, and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for migration, erosion, and/or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation, walking);

g. the propensity of the Products to cause a chronic inflammatory and fibrotic reaction and result in continuing injury over time;

h. the propensity of the Products to cause longstanding inflammatory response altering the effective porosity of the mesh, resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage, and neuromas; and

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

86. Defendant also breached its duty by negligently failing to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensity to contract, retract, and/or shrink inside the body;

b. The Products' propensity for migration and erosion;

c. The Products' inelasticity, preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal and/or pelvic scarring as a result of the Products;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual relations;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

k. The need for corrective or revision surgery to adjust or remove the Products, which in some cases is not feasible nor possible;

l. The severity of complications that could arise as a result of implantation of the Products;

m. The hazards associated with the Products;

n. The Products' defects described herein;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible, available, and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available, and safer alternatives;

q. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible, available, and safer alternatives;

r. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible, available, and safer alternatives;

s. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

t. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

u. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries because of implantation of mesh.

87. Defendant likewise failed to conduct post-market vigilance or surveillance to correct the Products' unreasonably dangerous condition by:

a. Failing to monitor or act on findings in the scientific and medical literature;

b. Failing to monitor or act on information received from physicians and women implanted with the Products;

c. Failing to monitor or investigate reports in the FDA adverse event databases for their potential significance for Defendant's Pelvic Mesh Products; and

d. Failing to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

i. Failing to report MDRs (Medical Device Reports); and

ii. Failing to investigate reports of serious adverse events.

88. As a direct and proximate result of Defendant's negligence, Plaintiff has sustained and will continue to sustain economic loss, severe and debilitating injuries, serious bodily injury, and mental and physical pain and suffering.

89. Boston Scientific has intentionally and/or recklessly designed, marketed, labeled, sold, and distributed the Products with wanton and willful disregard for the health of Plaintiff and others. With malice, Boston Scientific placed their economic interests above the health and safety of Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory and punitive damages together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: NEGLIGENT MISREPRESENTATION

90. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

91. Boston Scientific owed a duty to individuals, including Plaintiff, to provide accurate and non-misleading information about their Products' safety and efficacy.

92. As a consumer of Boston Scientific's Products, it was foreseeable that Plaintiff would hear, read, and/or otherwise rely on Boston Scientific's marketing, labeling, and publications regarding product safety.

93. Prior to Plaintiff's implantation of the Obtryx Transobturator Mid-Urethral Sling System (Lot Number: 22517186) on August 16, 2019, Defendant made numerous misrepresentations regarding the Products to Plaintiff and Plaintiff's physicians, including the Product implanted in Plaintiff, including, but not limited to that:

a. the Products were safe, effective, and reliable medical devices;

b. the Products were implanted by way of safe, effective, reliable, and minimally invasive surgical techniques;

c. the Products were a viable option for surgeons to use for SUI and POP repair;

d. the Products were safer and more effective options than alternative treatments of SUI and POP;

e. the Products did not carry substantial risks, dangers, and defects;

f. the adverse events associated with the Products were insubstantial and infrequent; and

g. the Products would not require frequent and invasive revision and excision surgeries.

94. Boston Scientific had no reason to believe the above listed misrepresentations were true. Indeed, Boston Scientific knew and/or should have known those representations were false.

95. The above listed misrepresentations were intentionally directed at consumers of Boston Scientific's Products, including Plaintiff.

96. The safety profile of the Products, which was based off Defendant's misrepresentations, was material to Plaintiff and her physicians' decision to implant the mesh. Plaintiff and her physicians believed those facts associated with the safety profile to be true.

Plaintiff and her physicians acted in reasonable reliance on Boston Scientific's misrepresentations, and those acts resulted in injuries that Plaintiff suffered and will continue to suffer.

97. As a direct and proximate result of Defendant's misrepresentations, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, and mental and physical pain and suffering. She has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses and lost income, and she has suffered other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory and punitive damages together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VIII. PRAYERS FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

A. Judgment in favor of Plaintiff and against Defendant for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including, but not limited to, medical expenses, disfigurement, pain and suffering, and mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Restitution and disgorgement of all revenue that Defendant has obtained through the manufacture, marketing, sale, and administration of the Pelvic Mesh Devices;

D. Attorneys' fees and costs where applicable;

E. Pre-and post-judgment interest; and

F. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: 6/20/2025

Respectfully submitted,

/s/ Robert T. Naumes, Jr.
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